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NEUROSURGERY

December 1, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket #97N-484S

To Whom It May Concern:

As a Board Certified Neurosurgeon, I have used bank bone (allograft) for almost 20 years. It is an essential part of many spinal surgical procedures and the ability to use bank bone results in decreased morbidity from graft harvesting in patients. The safety and efficacy of allograft is well documented in the literature and the risks of viral transmission are minimal. With this in mind, I implore you to refrain from imposing legislation on bone banks that would curtail the supply of allograft. While reasonable evaluation of new products certainly is required, bone products and allograft has been utilized for over 40 years. It does not make good common sense to re-invent the wheel at the risk of placing increased morbidity upon patients.

Again, I implore you to use common sense and ensure that an adequate supply of allograft bone be available for spinal surgery.

If I can provide any further information, please feel free to contact me directly.

Sincerely,



Peter M. Klara, M.D., Ph. D.

PMK/mat:jjk

DT: 12-01-99

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"DICTATED BUT NOT READ"

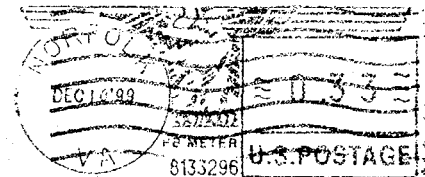
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